GROWING UP TOBACCO FREE

PREVENTING NICOTINE ADDICTION IN CHILDREN AND YOUTHS

Barbara S. Lynch and Richard J. Bonnie, *Editors*

Committee on Preventing Nicotine Addiction
in Children and Youths

Division of Biobehavioral Sciences and Mental Disorders

Institute of Medicine

NATIONAL ACADEMY PRESS
Washington, D.C. 1994

CONTENTS

8 REGULATION OF THE LABELING, PACKAGING, AND CONTENTS OF TOBACCO PRODUCTS

TOBACCO: AN UNREGULATED HAZARD

Food products, bicycles, automobiles, matches and lighters, pharmaceuticals, and other consumer products are subject to a variety of federal regulatory statutes. These laws typically authorize administrative agencies to require manufacturers to reduce the risks associated with the use of the product or even to ban products that are unreasonably dangerous. Tobacco products, however, have been excluded from the coverage of these federal regulatory schemes, either by explicit statutory exemption or by agency practice. For example, the enabling legislation for the Consumer Product Safety Commission, the Consumer Product Safety Act of 1972 (CPSA), expressly excludes tobacco from its otherwise broad delegation of power to regulate consumer products that present an "unreasonable risk of injury." Shortly after a federal court ruled that the Consumer Product Safety Commission had jurisdiction to regulate high-tar tobacco products under the Federal Hazardous Substances Act, Congress amended that act to exclude tobacco from the definition of "hazardous substances."[1] Similarly, the Toxic Substances Control Act expressly exempts tobacco from regulation even though the constituents of tobacco smoke might otherwise be subject to regulation as "chemical substances which present unreasonable risk of impairing health," or as "mixtures of such substances."[2] Despite its addictiveness, tobacco is also specifically exempted from the Controlled Substances Act, which regulates the medical and scientific use of other psychoactive drugs and prohibits their distribution and use for nonmedical and nonscientific purposes.

It is not difficult to understand why Congress has excluded tobacco from

these regulatory schemes. If tobacco products were included, each of these statutes would require extensive regulation of tobacco products to reduce risks to the health and safety of users and nonusers, including changes in product design and mandatory disclosure of information regarding contents and hazards. Moreover, under most of these schemes, faithful adherence to the statutory criteria would authorize, or even require, the regulatory agencies to take tobacco products off the market. For example, the chronic risk of tobacco products is much greater than the hazards of other products that have been banned under the Consumer Product Safety Act, and the Consumer Product Safety Commission's priority-setting rule suggests that it would have no choice but to ban tobacco products as well.

An analogous problem arises under the Food, Drug, and Cosmetic Act (FDCA). The definition of "drug" in the FDCA includes "articles (other than food) intended to affect the structure or any function of the body of man." Although the act does not expressly exclude tobacco products from its coverage, the Food and Drug Administration (FDA) has long taken the position that tobacco products manufactured and sold to be used "for smoking pleasure" are not "drugs" under the FDCA and are not subject to regulation thereunder, in the absence of *intent* by the manufacturers or vendors of cigarettes to affect the structure or function of the body. This position was ratified by the courts and has become the settled understanding.[3]

The FDA has not declined to exercise jurisdiction over tobacco products in all cases. The FDCA's definition of drug also includes articles "intended for use in the cure, mitigation, or prevention of disease," and the FDA has asserted jurisdiction when manufacturers have expressly promoted cigarettes as beneficial to health. For example, during the 1950s, the agency took regulatory action against cigarettes advertised as effective in preventing respiratory and other diseases[4] and cigarettes promoted as weight-reducing aids.[5] The FDA has also exercised jurisdiction over cigarette additives promoted as mitigating disease and over nicotine delivery systems promoted as alternatives to conventional cigarette smoking or as aids to smoking cessation. In recent years, petitions have been filed seeking to invoke FDA jurisdiction over cigarettes promoted as being "light" or otherwise low in tar and nicotine on the basis that these assertions imply that the cigarettes are less dangerous than other cigarettes and less likely to result in dependence or disease. The FDA has not yet acted on these petitions.

On February 25, 1994, FDA Commissioner David Kessler indicated that the agency was reconsidering its traditional view that tobacco products are not "drugs" under the FDCA. In a letter to the Coalition for Smoking OR Health and in subsequent testimony on Capitol Hill, Dr. Kessler sought to focus attention on whether cigarettes and other tobacco products are marketed as "nicotine delivery systems" to satisfy the dependence of consumers on nicotine. In raising this question, Dr. Kessler referred to evidence that "manufacturers commonly add nicotine to cigarettes to deliver specific amounts of nicotine."[6] (As was

subsequently discussed at hearings before the House Subcommittee on Health and the Environment, cigarette manufacturers remove nicotine and add it back, in the form of tobacco extract, in the manufacturing of cigaretttes with the desired level of nicotine.)[7] Although Dr. Kessler did not assert FDA jurisdiction, he stated that, in his view, a legal basis for regulation would be established by evidence proving that cigarette manufacturers intend that their products contain nicotine to satisfy an addiction on the part of some of their customers. At the same time, Dr. Kessler indicated that the agency was reluctant to move in this direction without explicit congressional authorization.

The FDA's longstanding reluctance to classify tobacco products as "drugs" under the FDCA is understandable. Under the regulatory logic of the FDCA, cigarettes (or other tobacco products) intended to produce or to satisfy nicotine dependence would have to be proven "safe and effective" in order to remain on the market. Tobacco products are demonstrably *un*safe. Thus, an inevitable effect of classifying nicotine-containing tobacco products as "drugs" would be to ban them. Yet, an agency ban under the FDCA arguably would be incompatible with a 30-year history of congressional action regulating the advertising and labeling of tobacco products while permitting their continued manufacture and use.

The net result of Congress' actions and inactions over the past 30 years is that tobacco products, as customarily manufactured, marketed, and consumed, are largely unregulated. The tendency of these products to produce addiction is currently without regulatory significance, notwithstanding extensive federal control over other dependence-producing drugs. In addition, the tendency of tobacco products to cause disease and premature death has no regulatory significance under any of the statutory schemes that regulate hazardous products, substances, or drugs. The only agency (FDA) with jurisdiction over any tobacco product now confines itself to peripheral situations in which a tobacco product is promoted as satisfying a desire for nicotine or as being effective in preventing or mitigating disease, and the agency is clearly reluctant to broaden its reach without explicit congressional direction.

The federal government's occasional regulatory initiatives have been severely circumscribed. Manufacturers of tobacco products are now required to provide a list of additives to the secretary of health and human services, but no agency has the authority to require disclosure of this information to consumers or to proscribe hazardous additives. (After a list of additives was obtained by the press in April 1994, the cigarette manufacturers jointly issued a combined list.) Although federal law requires that warnings about the health hazards of tobacco use be conveyed to purchasers on packaging and in advertising, no agency is directed by statute to monitor the efficacy of these warnings in discouraging youth initiation or other tobacco consumption, and no agency has the authority to require that the warnings be modified in light of advances in scientific and medical knowledge. Although the Department of Health and Human Services

has adopted the reduction of tobacco use (and of tobacco-related morbidity and mortality) as major public health goals, no agency has the responsibility for determining whether the achievement of these goals could be promoted by regulating the constituents of tobacco products. (Indeed, as discussed below, no agency in the Department of Health and Human Services has clear-cut regulatory authority to coordinate the federal government's programmatic efforts to achieve this goal.)

Congress must rectify this massive regulatory default. A comprehensive national strategy of tobacco control must include a regulatory component. Specifically, **Congress should enact legislation that delegates to an appropriate agency the necessary authority to regulate tobacco products for the dual purposes of discouraging consumption and reducing the morbidity and mortality associated with use of tobacco products.** Although the Committee has not designed a detailed blueprint, the Committee has formulated a general outline of such a regulatory scheme, focusing on the ways in which such a plan would help reduce nicotine dependency among children and youths.

A comprehensive statutory scheme for regulating tobacco products should include at least two major components: regulation of product labeling and packaging and direct regulation of the product itself. In each context, the overall regulatory aim is twofold: to discourage people, especially children and youths, from using tobacco products, and to reduce the morbidity and mortality associated with use of tobacco products. Difficult questions of regulatory design must be addressed in each context. Two major issues are (1) which agency or agencies should be assigned regulatory responsibility and (2) what criteria or standards should guide the exercise of regulatory authority.

WARNINGS AND PACKAGING

Congress has enacted a series of laws specifying that warnings be placed on cigarette packages, first in 1965, again in 1969, and most recently in 1984. Also, in 1986 Congress enacted warning requirements for smokeless tobacco products. However, Congress has never delegated the authority to update these warnings, or to evaluate their effectiveness, to a regulatory agency. The adequacy of the current cigarette warnings has been repeatedly questioned by public health specialists. Moreover, in the Committee's view federal cigarette labeling legislation has reflected an unsatisfactory compromise between the public's health and the tobacco industry's desire to avoid concurrent state regulation and to reduce its exposure to tort liability. Negotiations in the legislative process have tended to favor the industry. Inevitably, congressionally prescribed warnings have reflected political trade-offs rather than an unequivocal goal of providing relevant and complete health information.

The inadequacy of current labeling policy is clearly revealed in the declaration of congressional purpose in the Comprehensive Smoking Education Act of 1984:

> It is the purpose of this Act to provide a new strategy of making Americans more aware of any adverse health effects of smoking, to assure the timely and widespread dissemination of research findings, and to enable individuals to make informed decisions about smoking.[8]

It is time to state, unequivocally, that the primary objective of tobacco regulation is not to promote informed choice, but rather to discourage consumption of tobacco products, especially by children and youths, as a means of reducing tobacco-related death and disease. Even though tobacco products are legally available to adults, the paramount public health aim is to reduce the number of people who use and become addicted to these products, through a focus on children and youths. The warnings must be designed to promote this objective. In the Committee's view, the current warnings are inadequate even when measured against an informed choice standard, but they are woefully deficient when evaluated in terms of proper public health criteria.

The History of Federal Action

The publication of the 1964 report of the Surgeon General's Advisory Committee on Smoking and Health, linking cigarette smoking to lung cancer, chronic bronchitis, and emphysema, marked the emergence of a public consensus and stimulated federal regulatory and legislative action. In response to the surgeon general's call for "appropriate remedial action," the Federal Trade Commission (FTC) proposed rules requiring that manufacturers disclose on all packaging and advertisements that "cigarette smoking is dangerous to health" and "may cause death from cancer and other diseases." Before taking effect, however, the FTC regulations were preempted by the Cigarette Labeling and Advertising Act of 1965. In their place, the act mandated a mild health warning on cigarette packaging without specific reference to the risk of death from cancer and other diseases:

> Caution: cigarette smoking may be hazardous to your health.[9]

Unlike the proposed FTC regulations, the 1965 act did not require warnings on product advertisements. The act also divested federal agencies and states of the authority to impose more stringent health warning requirements. In particular, the FTC was prohibited from requiring health warnings on tobacco advertising for four years, until July 1, 1969, although the FTC's authority to regulate unfair or deceptive advertising was left intact. Vesting nearly exclusive regulatory authority in the Congress, the Cigarette Labeling and Advertising Act freed the tobacco industry of the threat of bolder regulatory action and removed the debate to a forum where public health objectives shared the stage with economic concerns and other political pressures.

In 1967, the Federal Communications Commission (FCC) ruled that the "Fairness Doctrine," which required television stations to provide air time for alternate points of view on matters of public debate, applied to tobacco commercials. Broadcasters who carried cigarette commercials were required to provide free air time to health groups, whose imaginative and effective antismoking commercials contributed to a general decline in smoking rates.[10] In 1969, the FCC announced its intention to ban cigarette advertising on radio and television and the FTC proposed requiring health warnings on cigarette advertisements. As in 1964, those agency initiatives provoked congressional action.

The Public Health Cigarette Smoking Act of 1969 amended the original 1965 labeling act to require a slightly strengthened health warning:

> Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health.[11]

Again, the congressionally mandated warning was milder than that recommended by the FTC and omitted specific reference to death, cancer, heart disease, chronic bronchitis, and emphysema. In addition, the act banned cigarette advertising on radio and television. Seeking to avoid the antismoking commercials mandated by the FCC's Fairness Doctrine, the tobacco industry staged little resistance to the broadcast ban. Again, Congress temporarily restricted the FTC from requiring manufacturers to include health warnings in print advertising until July 1, 1971. Congress also barred states from imposing "any requirement or prohibition based on smoking and health" on the advertising and promotion of cigarettes packaged with labels conforming to the statute. (The U.S. Supreme Court subsequently ruled in 1992 that this language not only preempted direct restrictions on advertising but also shielded the industry from liability in tort actions brought by or on behalf of injured smokers for failure to warn in advertising or promotion or for misrepresentation through overpromotion.)[12]

On March 30, 1972, the FTC and the cigarette companies agreed upon consent orders requiring all cigarette advertising to display, "clearly and conspicuously," the same warning required by Congress for cigarette purchases. The consent order specified the type size of the warnings in newspaper, magazine, and other periodical advertisements of various dimensions. The size of lettering was specified in inches for billboard advertisements.

In 1981, the FTC determined that the federally mandated health warnings had little impact on the public's level of knowledge and attitudes about smoking. In a staff report to Congress, the FTC concluded that the warning was "worn out," too abstract, difficult to remember, and not perceived as personally relevant.[13] The FTC report helped to spur Congress to enact the Comprehensive Smoking Education Act of 1984, which required four, more specific, rotating health warnings on all cigarette packages and advertisements:

> SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.

> SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.
>
> SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight.
>
> SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.[14]

Like the health warnings enacted by Congress in the past, the new warnings resulted from political compromises favorable to the tobacco industry, rather than from an unqualified effort to inform the public. The warnings retained the same rectangular format despite an FTC recommendation that a "circle-and-arrow" format would be more effective. The warnings contain no reference to addiction, miscarriage, or death and require no disclosure of tar, nicotine, and carbon monoxide yields.

Required warnings were extended to smokeless tobacco products by the 1986 Comprehensive Smokeless Tobacco Health Education Act. Under the act, three rotating warning labels must be displayed on smokeless tobacco packaging and advertising in the circle-and-arrow format that had been recommended by the FTC for cigarettes:

> WARNING: This product may cause mouth cancer.
>
> WARNING: This product may cause gum disease and tooth loss.
>
> WARNING: This product is not a safe alternative to cigarettes.[15]

Federal agencies and state and local governments are preempted from imposing additional health warnings on smokeless tobacco products and advertisements.

The Importance of Warnings in Discouraging Use by Youths

In theory, tobacco health warnings are particularly relevant to persons who are experimenting with or deciding whether to use tobacco but who have not yet become regular users. Accordingly, since regular tobacco use is usually established before the age of 18, children and youths are an important target for health messages. Warnings that do no more than accomplish their original purpose—to promote informed choice—can increase the availability and salience of health risk information every time a young person decides whether to buy or use tobacco. However, tobacco health warnings should also aim to discourage tobacco use, not only by providing information regarding the harmful consequences of tobacco, but also by vitiating the appeal of advertising and promotion and by sending an unequivocal anti-tobacco message. In the Committee's view, strong health warnings, and accompanying package regulation, are an important component of a coordinated plan to reduce and prevent tobacco use by children and youths.

The Inadequacy of Existing Warnings

No published studies have directly evaluated the impact of the federally mandated tobacco health warnings on knowledge or behavior of adults or youths. Isolating the independent effects of the warnings themselves from the effects of other policies that discourage tobacco use and from the effects of other sources of information regarding smoking is a daunting, if not impossible, task. As the surgeon general recently stated, "there are no controlled studies that permit definitive assessment of the independent impact of cigarette warning labels on knowledge, beliefs, attitudes, or smoking behavior."[16] However, a body of indirect evidence suggests that the current warnings are probably not having the desired impact on knowledge or behavior, especially among youths.

It is clear, first of all, that adolescents continue to underestimate the adverse health consequences of tobacco use. Although they understand that smoking is hazardous and can associate smoking with particular health risks, adolescents underestimate the magnitude of the risks of regular smoking over the long term.[17] As discussed in chapter 1, adolescents do not appreciate the risk and consequences of becoming addicted. As a result, according to the University of Michigan's Monitoring the Future Study, *nearly half* (47%) of eighth graders in 1993 denied that there is "great risk" associated with smoking a pack of cigarettes per day. Even among high school seniors, more than 30% denied that there was a "great risk" associated with pack-a-day smoking. Only 35% of high school seniors reported believing that "great risk" was associated with regular use of smokeless tobacco.[18]

Steps must be taken to improve youngsters' awareness of the long-term dangers of tobacco use. The Committee is not suggesting that changes in warnings alone can produce the desired effects. Adolescents' deficient understanding of the adverse health consequences of tobacco can also be remedied by anti-tobacco media campaigns and by educational programs. Nonetheless, the potential contributions of improved warnings should not be ignored. The research literature strongly suggests that the desired impact of the current warnings is eroded by remediable deficiencies in format, composition, and content.

In a recent review of research on consumer response to labeling information, the 1994 report of the surgeon general concluded that two basic factors appear to influence the usefulness of warning labels:

> First, to have an impact on consumers, warning labels must be designed to take into account those factors that might influence consumer response (e.g., a consumer's previous experience with the product, previous knowledge of the risks associated with the product's use, and level of education or literacy). Second, the labels should be designed in an attention-getting format, and the information they bear should be specific rather than general and written in clear, nontechnical language.[19]

It appears to be generally agreed that the present cigarette warnings are easily

and often overlooked, especially in contrast with the vibrant allure of tobacco packaging and advertising. Studies suggest that adolescents often do not notice or do not read the current warning labels.[20] The labels are small and inconspicuously located on the side of a package or in the lower corner of a print advertisement. They are often printed in colors that allow the warnings to blend in with packaging design or to be overwhelmed by the marketing imagery. Using an eye-tracking technique commonly used in market research, one study found that only 37% of adolescents viewing tobacco advertisements looked at the health warning long enough to read its words; 43.6% of the subjects did not look at the warning at all.[21] A similar response was found in a study of smokeless tobacco product packaging, in which only 43% of subjects noticed the warning label.[22]

Novel, eye-catching designs, such as the circle-and-arrow format recommended by the FTC and adopted by Congress for smokeless tobacco products, may increase noticeability.[23] The color and reflectiveness of the warning label in the context of the overall packaging or advertisement is also likely to affect noticeability. By requiring the warning to be printed in black and white, recent reform of tobacco labeling laws in Canada sought to prevent manufacturers from successfully blending the warning into the overall packaging. This concern is also addressed in H.R. 3614, introduced by Congressman Waxman in November 1993, which would require labels to be printed in white letters on a black background or black letters on a white background, whichever is more conspicuous, with the words "SURGEON GENERAL'S WARNING" printed in red and enclosed by a contrasting border.

To increase noticeability, Canada and Australia recently increased the size of warning labels, requiring the warning and its borders to occupy 30-40% of the display area of the package. The proposed H.R. 3614 also takes this approach, requiring the size of warning labels to occupy at least 25% of the side of the package on which they appear or 25% of the print advertisement. H.R. 3614 also would require the size, thickness, and typeface of the warning's lettering to be as "legible, prominent, and conspicuous" as any other lettering on the package or advertisement.

Studies also suggest that the current warnings are too small and too lengthy to be read in outdoor advertising media. A study of roadside billboards found that, under typical driving conditions, observers could read the entire warning message on only 5% of tobacco advertisements. Similarly, stationary observers were unable to read the health warnings in any of the tobacco ads on 100 New York taxicabs. In both media, however, observers were nearly always able to identify the brand name, advertising content, and imagery.[24] A study of the legibility of health warnings on cigarette billboards in Australia obtained similar results.[25]

Regulation of the other areas of the package can also help maximize the salience of the health warnings. One study found that existing tobacco packag-

ing conjured specific brand images in the minds of adolescents, such as "rugged" or "classy." Large, clashing warning labels were found to vitiate the attractiveness of the pack images. In particular, "plain packaging," in which the brand name is presented on a plain, standardized background and all logos and identifying information other than the brand name are removed, was found to effectively destroy the positive images created by cigarette packaging (figure 8-1).[26]

Warnings are likely to become less effective with time as they become "worn out." An unchanging shape, size, and heading in the warning may discourage further exploration of the message. Novel formatting is more likely to capture attention.[27] The retention of the original rectangular shape of the pre-1985 warning may have diminished the potential communication effectiveness of the more explicit rotating warnings.[28] Periodically altering the format of the warnings may help to refresh their impact.[29]

Preliminary studies on the effects of labels on alcoholic beverage containers suggest that warnings on health risks are likely to be most effective in increasing awareness of the least-known risks. Although warnings can serve as a reminder of already known hazards (such as impaired driving), they might be more useful for conveying specific information that is not widely known. One study found that the most readily recalled portion of the alcohol label was the message about

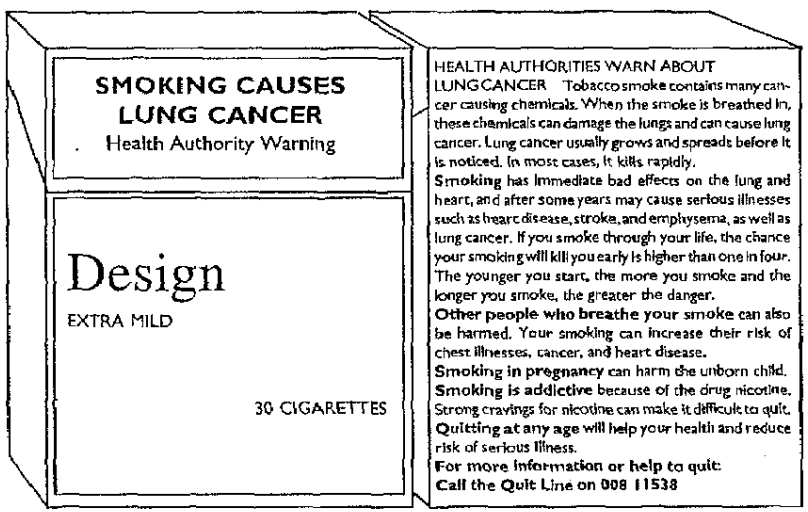

FIGURE 8-1 Proposed prototype of plain packaging for cigarettes in Australia. The per cigarette amounts of tar, nicotine, and carbon monoxide are listed and explained on the side panels.

birth defects.[30] Another found that, compared to baseline, there was no statistically significant change in knowledge of the health risks included in the labels but that awareness of two risks *not* included (risk of cancer and high blood pressure) declined from already low levels. These investigators concluded that it is "certainly plausible that rotating messages so as to keep them 'fresh' while increasing exposure to lesser known facts, could be a useful strategy to consider, and rigorously evaluate, in the future."[31]

Even when tobacco health warnings are noticeable and legible enough to be read, research suggests that the current warnings are not framed to be optimally understandable, believable, persuasive, and memorable.[32] In a recent study using standard market research techniques for evaluating advertisements, the congressionally mandated warnings performed poorly in communicating specific risk information. Although 79% of subjects exposed to the warnings reported the presence of a health message, only 15% reported the concept of the message and only 6% reported its exact content. On the other hand, the elements of the cigarette advertisements were frequently recalled: 97% of the subjects identified the brand of cigarettes being advertised.[33]

The impact of the current cigarette labels may be lessened by the fact that three of the four are framed in an impersonal manner. Readers are more likely to believe and heed warnings they perceive as personally relevant.[34] Using a larger number of rotating warnings is also more likely to provide a reader with one or several messages that will be perceived as personally relevant. H.R. 3614 proposes nine rotating warnings. Australia has chosen twelve rotating warnings and Canada has adopted eight. Using a larger number of rotating messages may also help to prevent the messages from becoming "worn-out" over time.

The power of the current warnings may also be diluted by wordiness and by combining several potential outcomes. One of the labels combines lung cancer, heart disease, emphysema, and pregnancy complications and another groups fetal injury, low birth weight, and premature birth. Short, concise, straightforward messages are thought to be the best vehicle for health warnings. For example, in a focus group study using adolescents to evaluate tobacco warnings labels, researchers found that the statement "Cigarettes kill. One in every 3 smokers will die from smoking." was perceived as direct and informative.[35] Lessons of this kind underlie one of the provisions of H.R. 3614, which would require shorter, more explicit statements than those currently used, including, "Cigarettes can kill you" and "Smoking during pregnancy can harm your baby."

Even if the current warnings were communicated effectively, they would fail to achieve Congress' stated purpose to "assure the timely and widespread dissemination of research findings" regarding the effects of smoking. The current warnings do not incorporate the substantial body of scientific knowledge that has accumulated since 1984 regarding the link between tobacco use and disease, the addictiveness of nicotine, the harmfulness of environmental tobacco smoke, and the dangers of chemical additives and byproducts. They omit any

reference to death, addiction, miscarriage, stroke, infant mortality, and danger to nonsmokers. With regard to nearly all other consumer products, Congress has delegated power to federal agencies to allow flexible regulatory choices regarding the content of mandatory package warnings or package inserts. The legislative process is ill-suited to the task of evaluating the quality of health warnings in light of ongoing scientific advances.

In sum, studies on communication of health messages demonstrate that consumer response to warning labels depends on the format and presentation of the message, as well as on its content. The current tobacco health warnings are inadequate to attract attention or to communicate relevant and up-to-date information. For greater impact, the format and content of the warnings must be designed with the same communication techniques used to craft the pro-tobacco messages with which they must compete.

Recent Initiatives in Other Countries

Canada recently amended its Tobacco Products Control Act to require larger, more legible, and more potent health warnings. Under previous requirements that labels be in "contrasting colors," many manufacturers used color combinations that blended into the overall package design or that were highly reflective of light and thus difficult to read at the point of sale. The insufficiently noticeable and legible warnings were thought to undermine their overall credibility. In addition, surveys found that Canadians had only a superficial knowledge of the health effects of smoking, demonstrating that the then-required warning labels were not achieving their purpose of adequately informing the public. The amended law requires that all sides of tobacco packaging display one of eight rotating warnings, including messages about addiction, death, and passive smoking. The black-and-white warnings with their surrounding borders must occupy from 30% to 40% of the main display area of the package. Display of information regarding the toxic constituents present in cigarette smoke is also required.[36] Also, in Canada the Tobacco Products Control Act required outdoor billboards erected after January 1, 1991, to carry a health message equal to 20% of the top portion of the sign. Billboards began disappearing, as manufacturers were unwilling to risk the impact of large health warnings on sales.[37]

Australia has recently strengthened its regulation of tobacco warning labels and packaging. In 1992, the Ministerial Council on Drug Strategy agreed that states would adopt twelve rotating warning labels at the top and front of cigarette packages, including warnings stating: "Smoking kills" and "Smoking is addictive." The recommendations also call for display of information on tar, nicotine, and carbon monoxide yields on the side of the pack, and detailed health information about the hazards of smoking to appear on the entire back of the package. The back of the package also provides a "Quitline" telephone number to call for further information about health risks and help with quitting smoking.

Recommendations for Health Warnings and Packaging of Tobacco Products

Given the current lack of regulation of tobacco products and the inadequacy of current labeling requirements, the Committee makes the following recommendations:

1. Congress should take steps to strengthen the federally mandated warning labels for tobacco products. Health warning labels should be optimally noticeable, believable, and informative, especially to children and youths. The existing warnings fail to communicate current and comprehensive health risk information in an effective way.

2. Congress should take steps to increase the salience and effectiveness of health warnings on both advertising and packaging. This can be accomplished by regulating the format and design of the warning and the amount of area of the package devoted to the warning. "Plain packaging" should be considered.

3. Based on current knowledge, Congress should enact specific warning and format requirements now, and should delegate regulatory responsibility for future modifications to the secretary of health and human services. The secretary should ensure that ongoing research is conducted on the effectiveness of prescribed warnings. Congress lacks the institutional expertise and flexibility to monitor the efficacy of regulatory innovations and to respond to new information. Authority to amend the warnings should be delegated to an appropriate regulatory agency. **The secretary should be empowered to modify the format or content of existing warnings and to prescribe additional warnings, whenever such action is reasonably necessary to achieve effective communication of significant information regarding the health consequences of tobacco use or to discourage consumption of tobacco products.**

4. To the extent that promotional use of logos and trademarks of tobacco products is legally permitted, Congress should make accompanying health warnings mandatory. The tobacco industry has substantially increased its marketing budget for the sponsorship of public events and for promotional uses of non-tobacco products such as clothing, sports equipment, caps, and lighters. Trademarks and logos associated with tobacco products are pervasively displayed. Promotional items are often especially appealing to children and youths and project positive lifestyle images of the decision to use tobacco products without a counterbalancing health message. This is why Congress decided to require manufacturers of smokeless tobacco products to affix health warnings on promotional items using their insignia, logos, and trademarks. Unfortunately, Congress has not enacted parallel legislation for cigarettes, and this omission should be rectified as soon as possible. The data in the most recent FTC report on tobacco advertising indicate that there has been a shift from traditional mass

media advertising to non-media promotions that are not required to carry health warnings.[38] Eventually, however, Congress should ban the promotional use of insignia, logos, and trademarks of all tobacco products, as recommended in chapter 4.

REGULATION OF CONSTITUENTS OF TOBACCO PRODUCTS

A Unique Regulatory Challenge

A regulatory plan should be designed and implemented to discourage tobacco use, especially by children and youths, and to reduce the morbidity and mortality associated with tobacco use. A bill along those lines has been introduced in the House by Representative Synar and the Committee anticipates that an analogous bill will be introduced in the Senate by Senator Kennedy. Although the Synar bill would confer jurisdiction on the FDA, it recognizes that the regulatory regime already established by the Food, Drug, and Cosmetics Act is a poor fit for the regulation of tobacco products. As noted by Commissioner Kessler in his statement of March 25, 1994, to the House Subcommittee on Health and the Environment, if nicotine-containing cigarettes were regulated as drugs, "strict application of [the FDCA] could result in the removal from the market of tobacco products."[39] However fervently such a policy might be sought by public health advocates, the regulatory premise must be that tobacco products will remain lawfully available for adult consumption.

Once the continued lawfulness of tobacco products is acknowledged, legislative architects must confront a daunting challenge of regulatory design. As a nation, we have experience in designing and administering regulatory schemes under which dangerous products are not lawfully available outside tightly controlled channels of distribution. The Controlled Substances Act is illustrative. We also have experience in designing and administering regulatory schemes under which easily available consumer products are regulated to reduce the risks of injury or disease. Promulgation of safety standards for all-terrain vehicles and cigarette lighters under the Consumer Product Safety Act is illustrative. However, we have little experience with regulating dangerous products that are legally available but whose use is nonetheless discouraged. Even in the analogous contexts of alcohol and firearm regulation, the prevailing regulatory aim is to control the conditions and consequences of use, not to discourage it altogether.

For the foreseeable future, tobacco products will remain lawfully available for use by adults and will be accessible to minors as well, despite the prohibition on sales to youth. Therefore, the Committee recommends: **Congress should confer upon an administrative agency the authority to regulate the design and constituents of tobacco products whenever it determines that such regulation would reduce the prevalence of dependence or disease associated with use of the product or would otherwise promote the public health. The agency should be specifically authorized to prescribe ceilings on the yields of tar, nicotine, or any other harmful constituent of a tobacco product.**

The Regulatory Agency

Authority to regulate tobacco products should be exercised by a public health agency within the Department of Health and Human Services. Whether such authority should be delegated to the FDA or to a free-standing tobacco control agency requires careful study by the Secretary of HHS and by the Congress. The scientific expertise, independence, regulatory experience, and credibility of the FDA weigh in favor of a delegation to that agency. However, there are many countervailing concerns. The addition of a major new regulatory responsibility could impair the FDA's ability to carry out its many other important responsibilities. Moreover, part of the regulatory agenda—discouraging tobacco consumption—diverges considerably from the FDA's established mission of assuring the safety and efficacy of socially useful products. In carrying out its customary task of assuring the safety of food, cosmetics, pharmaceuticals, and medical devices, the agency's protective role serves the general interest of the regulated industries as well as that of the consumers; the relationship between FDA and the manufacturers therefore has a collaborative dimension. By contrast, regulation of tobacco would put the agency in an adversarial battle with the tobacco industry. For these reasons, this unique regulatory task might be accomplished more successfully, and at less risk, by an agency (a tobacco control administration) with a unitary mission.

The Committee has no strong views on the issue, although it does lean slightly in the direction of a separate agency. However, if authority were to be delegated to the FDA, the new responsibility should be assigned to a new bureau within FDA with a distinct budget, and should be accompanied by adequate resources to carry out the regulatory mission without impairing the agency's ability to fulfill its many other responsibilities.

Possible Regulatory Initiatives

The agency's regulatory attention should encompass nicotine, tar, and other dangerous constituents of tobacco products, including those added by the manufacturer or produced as byproducts of mainstream or sidestream smoke. The main focus of regulatory attention should be on tar and nicotine. However, the agency should also consider possible means of reducing the specific toxins in tobacco smoke, regardless of whether they are in gas or particulate phase.

A regulatory agenda relating to tar and nicotine cannot be formulated with-

out confronting and resolving the ongoing debate about the possibility of a "less hazardous" cigarette. Most public health advocates are skeptical about the utility of efforts to shift smokers toward low-tar, low-nicotine brands in light of clear evidence that smokers compensate for the reduced nicotine content by inhaling more deeply and more frequently or by blocking vent holes in the filters. In fact, the industry has been criticized for promotional activity that allegedly implies, incorrectly, that "light," reduced tar and nicotine cigarettes are less hazardous. Tobacco control advocates have relied on these "implied health claims" to invoke FDA jurisdiction on the theory that those cigarettes are being promoted to prevent disease, and therefore are "drugs" for purposes of the FDCA.

The actual yield, that is, the amount taken in by people, from particular cigarettes, varies considerably among smokers. As discussed in chapter 2, this is because the standard yield is measured by a machine that smokes cigarettes in a mechanical and standardized way, whereas smokers can smoke their cigarettes with different numbers of puffs, different depths of inhalation, and the like. It is unknown whether there is a relationship between a person's smoking behavior (and therefore actual yields for particular cigarettes) and the person's degree of nicotine dependence or other individual factors. There is evidence that reduction of cigarette yields, particularly comparing the older unfiltered cigarettes to the modern filtered ones, has somewhat reduced the risks of lung cancer and chronic lung disease, although not the risk of coronary heart disease, caused by cigarette smoking.[40] It is unknown if different brands of modern filtered cigarettes with different yields of tar and nicotine produce different risk levels for disease. In any case, it is possible that products with particularly low yields, if the yields are confirmed to be low by measurements in human smokers, would have some advantage in public health terms for smokers who are unable to quit. Satisfactory information for addressing the comparative harmfulness of tobacco products will be available only if a methodology is developed for ascertaining actual yields in human consumers; only then will there be a scientific basis for deciding whether or not to develop a regulatory program centered on reducing yields of tar or nicotine.

Thus, **the regulatory agency, as its first step, should develop a sound methodology for ascertaining the actual yields of nicotine, tar, or any other constituents of tobacco products, based on human consumption.** Human exposure to some constituents of tobacco smoke can be assessed by use of biochemical markers of exposure to those constituents, although at present this methodology is technically difficult and still imprecise; however, it is likely that better exposure measures will be developed in the future. In any case, even the currently available measures of human exposure are likely to provide a better indicator of relative risk than do the standard cigarette smoking machine yields. At a minimum, the smoking machine tests can be modified to reflect the range of ways in which people actually smoke, including numbers of puffs and blocking of ventilation holes, to determine likely *ranges* of delivery. In addition, the

manufacturers of tobacco products could be directed to submit information to the regulatory agency regarding the actual yields of their products in humans for particular brands of tobacco products, based on use of prescribed protocols.

A variety of regulatory initiatives relating to tar and nicotine yields can be envisioned. **At a minimum, the regulatory agency should take steps to inform consumers about the meaning of statements regarding tar and nicotine yields, and particularly about the behavioral influences on intake, and the relative importance of the characteristics of the cigarette and the way it is smoked.**[41] The agency might also require that tar and nicotine yields be presented in a standard format, such as absolute content together with a statement of the range of expected systemic yield determined according to number of puffs or other behavioral factors. Currently, marketed cigarettes typically *contain* 8-9 mg nicotine in the tobacco rod, and have an expected actual yield to the smoker of 0.5-3.0 mg nicotine. Stating the nicotine content of the tobacco contained in the cigarettes is important because the content reflects the maximum possible yield, and reduction of content would be expected to result in a reduction in actual yield. Manufacturers might be required to convey this information on the package or through package inserts. In order to avoid misunderstanding, the agency might require consumers to be told that small differences in nominal yield do not reflect significant differences in health risks. Regulations of this nature will improve risk perception among consumers, and will correct any misleading impression about the relative hazards of cigarettes with different levels of tar and nicotine.[42] From the same perspective, the agency should be authorized to ban or regulate use of misleading terms (such as "light") in advertising or on packaging, and should be authorized to require the use of standard terms.

If the regulatory agency finds that reduction of tar and/or nicotine yields would reduce morbidity or mortality associated with use of tobacco products, it should be authorized to prescribe ceilings of tar and/or nicotine yields and to develop a regulatory program of phased reductions in those ceilings over time.

Tar and nicotine yields are closely linked in cigarette smoke. However, it is possible for the manufacturer to unlink them and, as noted earlier, there is evidence that cigarette manufacturers currently manipulate the nicotine yield. The possibility of unlinking tar and nicotine yields has led researchers and public health officials to consider a variety of regulatory strategies. One possibility is a low-tar cigarette that would reduce health risks while providing satisfactory levels of nicotine sought by addicted users. Although this strategy is inherently limited by the fact that the taste of cigarettes is associated with the constituent toxins, it should be explored by the regulatory agency. The potential for reduced levels of tobacco toxins independent of changes in nicotine may be greater for smokeless tobacco.

Another possibility would be to focus directly on reducing the nicotine content as a strategy for reducing addiction and therefore, ultimately, for reducing

exposure to the harmful effects of tobacco products. A coordinated strategy of reducing tar and nicotine yields in tandem could also be envisioned.

Public health officials in the United States have heretofore been reluctant to pursue a policy of reducing the tar and nicotine content of tobacco products because of concern about misleading consumers or potential consumers into thinking that tobacco use can be safe. However, international health officials and policymakers in other countries have endorsed and implemented such policies.

International support has been growing for ceilings on tar content. The World Health Organization and the International Union Against Cancer (UICC) have endorsed a goal of reducing tar content of cigarettes to 15 mg. The UICC recommends a progressive eradication of high-tar brands from the market, starting with brands over 25 mg, then 20 mg, and then 15. The European Community has issued a directive requiring its member states to set an upper limit to 15 mg, falling to 12 mg in 1995.

FDA Commissioner Kessler has recently initiated public discussion of nicotine regulation as a primary regulatory strategy. One possible goal of a nicotine reduction strategy might be to reduce the nicotine content below the level that is likely to produce addiction. Based on the intake of cigarette smokers who appear not to be addicted (that is, who smoke less than five cigarettes per day), Benowitz and Henningfield have estimated that "5 mg of nicotine per day is a threshold level of nicotine that would readily establish addiction."[43] Extrapolating from this figure, they calculate that a maximum yield of 0.25 mg of nicotine per cigarette (considering the possible effects of compensatory increases in the intensity of puffing) might be adequate to prevent the development of addiction in most individuals. If the regulatory agency were to use a threshold concept of addiction as a basis for regulatory action, it might gradually depress the ceiling of allowable nicotine yield toward that threshold over a 10- to 15-year period.

A series of reductions in tar and/or nicotine yields would have to be carefully planned and gradually implemented. Imposition of such ceilings could result in the development of a black market in unregulated tobacco products, grown domestically or imported. There could also be substitution effects with different tobacco products or other nicotine delivery systems. It is also conceivable that a regulatory initiative favoring less hazardous tobacco products could lead to increased initiation, which could offset the public health gains among smokers. Thus, complex regulatory judgments will be required. It will also be necessary for the agency to monitor the effects of its regulatory policies in order to ensure that they promote the public health and that the benefits exceed the costs.

In conclusion, this is an important, complex regulatory agenda. It should be implemented with caution, but the complexity of the effort does not justify continuing refusal to undertake it. It is time for Congress to act.

A final caveat is in order. Recent discussions of the possibility of FDA

regulation have focused on nicotine. According to the emerging regulatory vocabulary, cigarettes and other tobacco products are "nicotine delivery systems." This new vocabulary is useful because it heightens public awareness of the addictive properties of tobacco products and reinforces the premise of this report—that preventing nicotine dependence among children and youths is an essential component of a coherent strategy for reducing the social burden of disease and death associated with smoking and chewing of tobacco.

It must also be remembered, however, that the social burdens of tobacco use are not associated with nicotine *per se*. Nicotine dependence is problematic because it causes use of tobacco, which in turn causes disease and dysfunction, and the nation's regulatory strategy must ultimately maintain a clear focus on the *adverse health effects of using tobacco*. Preventing nicotine dependence among children and youths is a means of protecting the public health, not an end in itself. As the nation moves along the path toward regulation of tobacco products, the focus should be on reducing harm related to use of tobacco. Similarly, classification of tobacco products as "nicotine delivery systems" should be described as a regulatory strategy for promoting the public health, not for winning a "war" against nicotine.

REFERENCES

1. O'Reilly, James T. "A Consistent Ethic of Safety Regulation: The Case for Improving Regulation of Tobacco Products." *Administrative Law Journal* 3 (1989): 235-250.
2. *Ibid.*
3. *Action on Smoking and Health v. Harris.* 655 F. 2d 236 (D.C. Cir. 1980).
4. *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes.* 113 F. Supp 336 (D. N.J., 1953).
5. *United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes.* 178 F. Supp. 847 (D. N.J., 1959).
6. Kessler, David A. Letter to Scott Balin, Coalition on Smoking OR Health. 25 Feb. 1994.
7. Hilts, Philip. "Tobacco Chiefs Say Cigarettes Aren't Addictive." *New York Times* (15 Apr. 1994): A1.
8. *Comprehensive Smoking Education Act of 1984.* P.L. 98-474. Section 2. 12 Oct. 1984.
9. *Cigarette and Labeling Advertising Act of 1965.*
10. Warner, Kenneth E. "Clearing the Airwaves: The Cigarette Ban Revisited." *Policy Analysis* 5:4 (1979): 435-450.
11. *Public Health Cigarette Smoking Act of 1969.*
12. *Cipollone v. Ligget Group, Inc.* 112 S. Ct. 2608 (1992).
13. Myers, M. L., C. Jennings, W. Lenox, E. Minsky, and A. Sachs. "Federal Trade Commission Staff Report on the Cigarette Advertising Investigation." *Federal Trade Commission Report* (May 1981).
14. *Comprehensive Smoking Education Act*, Sec. 4.
15. *Comprehensive Smokeless Tobacco Health Education Act of 1986.* P.L. 99-252. Section 3. 27 Feb. 1986.
16. Centers for Disease Control and Prevention. *Preventing Tobacco Use Among Young People: A Report of the Surgeon General.* S/N 017-001-004901-0. Washington, DC: U.S. Government Printing Office, 1994. 262.

17. Levanthal, Howard, Kathleen Glynn, and Raymond Fleming. "Is the Smoking Decision an 'Informed Choice'? Effect of Smoking Risk Factors on Smoking Beliefs." *Journal of the American Medical Association* 257:24 (26 June 1987): 3373-3376.

18. Johnston, L., J. Bachman, and P. O'Malley. "Monitoring the Future Study." Press release. The University of Michigan, Ann Arbor. January 27, 1994.

19. Centers for Disease Control and Prevention. *Preventing Tobacco Use*, 262.

20. Fischer, Paul M., John W. Richards, Earl F. Berman, and Dean M. Krugman. "Recall and Eye Tracking Study of Adolescents Viewing Tobacco Advertisements." *Journal of the American Medical Association* 261 (1989): 84-89.

21. *Ibid.*

22. Brubaker R. G., and S. K. Mirby. "Health-Risk Warning Labels on Smokeless Tobacco Products: Are They Effective?" *Addictive Behavior* 15 (1990): 115-118.

23. Myers et al.

24. Davis, Ronald M., and Juliette S. Kendrick. "The Surgeon General's Warnings in Outdoor Cigarette Advertising: Are They Readable?" *Journal of the American Medical Association* 261 (1989): 90-94.

25. Cullingford, R., L. Da Cruz, S. Webb, R. Shean, and K. Jamrozik. "Legibility of Health Warnings on Billboards that Advertise Cigarettes." *Medical Journal of Australia* 148 (1988): 336-338.

26. Centre for Behavioral Research in Cancer. *Health Warnings and Contents Labelling on Tobacco Products.* For Ministerial Council on Drug Strategy, Tobacco Task Force on Tobacco Health Warnings. Anti-Cancer Council of Victoria, Australia. 1992. 9-20, 31, 85-131.

27. Cohen, J., and T. Srull. *Information Processing Issues Involved in the Communication and Retrieval of Cigarette Warning Information. Report to the Federal Trade Commission.* Center for Consumer Research: University of Florida, 1980.

28. Bhalla, G., and J. L. Lastovicka. "The Impact of Changing Cigarette Warning Message Content and Format." *Advances in Consumer Research* 11 (1984): 305-310. Cited in Kaiserman, Murray. "The Effectiveness of Health Warning Messages." *Tobacco Control* 2 (1993): 267-269.

29. Myers et al.

30. Mayer, Robert N., Ken R. Smith, and Debra L. Scammon. "Evaluating the Impact of Alcohol Warning Labels." *Advances in Consumer Research* 18 (1991): 713.

31. Kaskutas, Lee, and Thomas K. Greenfield. "First Effects of Warning Labels on Alcoholic Beverage Containers." *Drug and Alcohol Dependence* 31 (1992): 1-14.

32. Beltramini, Richard F. "Perceived Believability of Warning Label Information Presented in Cigarette Advertising." *Journal of Advertising* 17:1 (1988): 26-32.

33. Fischer, Paul M., Dean M. Krugman, James E. Fletcher, Richard J. Fox, and Tina H. Rojas. "An Evaluation of Health Warnings in Cigarette Adverstisements Using Standard Market Research Methods: What Does It Mean to Warn?" *Tobacco Control* 2 (1993): 279-285.

34. Myers et al.

35. Fischer et al.

36. *Tobacco Products Control Act 1993.* P.C. 1993-1542. 21 July 1993. In *Canada Gazette Part II.* 127:16 (8 Nov. 1993): 3277ff.

37. Kaiserman, Murray. "The Effectiveness of Health Warning Messages." *Tobacco Control* 2 (1993): 267-269.

38. Federal Trade Commission. *Report to Congress for 1991. Pursuant to the Federal Cigarette Labeling and Advertising Act.* 1994. 15.

39. Kessler, David A. "Statement on Nicotine-Containing Cigarettes." To the House Subcommittee on Health and the Environment, U.S. Congress. 25 March 1994.

40. Benowitz, Neal L. "Health and Public Policy Implications of the 'Low Yield' Cigarette." *New England Journal of Medicine* 320:24 (15 June 1989): 1619-1621.

41. See for example: Kozlowski, Lynn. *Low Tar Cigarettes Are Hazardous to Your Health.* Toronto: Alcohol and Drug Addiction Research Foundation, 1993.

42. Viscusi, W. Kipp. *Smoking: Making the Risky Decision.* New York: Oxford Univerity Press, 1992.

43. Benowitz, Neal L., and Jack E. Henningfield. "Establishing a Nicotine Threshold for Addiction." *New England Journal of Medicine* 331:2 (1994): 123-125.